

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Applicant(s): Masahiro Endo et al.  
Appl. No.: 10/535,034  
Conf. No.: 3565  
Filed: December 16, 2005  
Title: DIALYSIS CATHETER SET AND METHOD OF USING SAME  
Art Unit: 3767  
Examiner: Catherine Witczak  
Docket No.: SMDI-5966 (112713-1362)

Mail Stop: Appeal Brief  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

February 19, 2009

**APPEAL BRIEF**

Sir:

Appellants submit this amended Appeal Brief in response to the Notice of Non-Compliant Appeal Brief mailed on February 13, 2009. Pages have been added for an Evidence Appendix and a Related Proceedings Appendix. No fee is due or owing for filing this paper.

Appellants submit this Appeal Brief in support of the Notice of Appeal filed on November 10, 2008. This Appeal is taken from the Final Rejection of claims mailed June 17, 2008, and the Advisory Action mailed on October 29, 2008. This Appeal Brief is timely filed.

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### **I. Real Parties in Interest**

The real parties in interest for the above-identified patent application on appeal are Baxter International Inc., Deerfield, IL, U.S.A., Fuji Systems Corporation, Tokyo, Japan, and Minoru Kubota, an individual residing in Japan, by virtue of an Assignment from all the inventors of record, the assignment recorded on May 13, 2005, at the United States Patent and Trademark Office at reel 017174, frames 0519 to 0524.

### **II. Related Appeals And Interferences**

Appellant's legal representative and the Assignee of the above-identified patent application do not know of any prior or pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision with respect to the above-identified Appeal.

### **III. Status of the Claims**

Claims 1-11 and 13-45 are pending in the above-identified patent application. Claims 1-11, 13-30 and 45 stand rejected. The rejection of Claims 1-11, 13-30 and 45 is presently appealed. Claim 12 has been cancelled. Claims 31-44 have been withdrawn pursuant to a restriction requirement and form no part of this appeal. A copy of the appealed claims is attached in the Claims Appendix.

### **IV. Status of the Amendments**

No amendment was filed in response to the final rejection. Therefore, no unentered amendments are pending in this case.

### **V. Summary of the Claimed Subject Matter**

A table of the claimed subject matter is herein presented, with reference to the drawings and specification as filed, for support of each of the independent claims, Claims 1, 16 and 23. No claims are in means plus function format or in step plus function format.

<b>Claim 1</b>	<b>Specification</b>	<b>Figures</b>
1. A catheter set for peritoneal dialysis comprising:	Page 7, lines 11-15.	Fig. 1, numeral 100.
a generally tubular catheter having first and second ends, an extraperitoneal portion near the first end and an intraperitoneal portion near the second end and a passageway defined by an interior surface extending from the first end to the intraperitoneal portion; and	P. 4, lines 28-30; p. 7, lines 11-15; p. 9, line 30, to p. 10, line 3; p. 15, lines 5-6.	Fig. 1, numeral 10 depicting a generally tubular catheter.
an insert extending along the passageway and comprising an elongated portion having an exterior surface which is sized relative to the interior surface of the catheter to achieve a snug fit between the interior surface of the catheter and the exterior surface of the insert, the insert defining a cavity and having an extraperitoneal end and an intraperitoneal end wherein the catheter further comprises a first plurality of side apertures formed on the intraperitoneal portion of the catheter and wherein the insert further comprises a second plurality of side apertures formed near the extraperitoneal end, the cavity being in fluid communication with the second plurality of side apertures.	p. 4, line 28 to p. 5, line 1; p. 10, lines 16-21; p. 11, lines 31-32; p. 12, lines 16-19; p. 15, lines 6-7; p. 20, lines 2-4.	Fig. 1, numeral 30 depicting a generally tubular insert.

<b>Claim 16</b>	<b>Specification</b>	<b>Figures</b>
16. A catheter set for peritoneal dialysis comprising:	Page 7, lines 11-15.	Fig. 1, numeral 100.
a generally tubular catheter having first and second open ends and comprising an extraperitoneal portion near the first end and an intraperitoneal portion near the second end and a passageway defined by an interior surface extending from the first end to the second end, and a first plurality of side apertures formed near the second end;	p. 4, lines 28-30; p. 7, lines 11-15; p. 9, line 30, to p. 10, line 3; p. 15, lines 5-6.	Fig. 1, numeral 10 depicting a generally tubular catheter.
an insert placed inside the catheter, the insert extending along the passageway and comprising an elongated portion having an exterior surface which is sized relative to the interior surface of the	p. 4, line 28 to p. 5, line 1; p. 10, lines 16-21;	Fig. 1, numeral 30 depicting a generally tubular insert.

catheter to achieve a snug fit between the interior surface of the catheter and the exterior surface of the insert, the insert defining a cavity and having an extraperitoneal end and an intraperitoneal end and a second plurality of side apertures formed near the extraperitoneal end; and	p. 11, lines 31-32; p. 15, lines 6-7; p. 20, lines 2-4.	
a guide placed in the cavity and extending from the extraperitoneal end of the insert.	p. 10, lines 23-27; p. 16, lines 19-20.	Fig. 1, numeral 50 indicating a guide for placement in the cavity of insert 30.

Claim 23	Specification	Figures
23. An obstructor for occupying space within a tubular catheter when inserted into a patient, the catheter defining first and second ends and a passageway defined by an interior surface extending between the first and second ends, the obstructor comprising:	P. 17, lines 7-9, 14-15.	Fig. 1, numerals 30 and 10.
a tube extending along the interior space of the catheter, the tube including an extraperitoneal end and an intraperitoneal end, a portion near the extraperitoneal end having an increased diameter and a plurality of side apertures, the portion contacting the first end of the catheter when the tube is inserted into the catheter, the intraperitoneal end of the tube extending at least substantially to the second end of the catheter, an outer diameter of the portion having an exterior surface which is sized relative to the interior surface of the catheter to achieve a snug fit between the interior surface of the catheter and the exterior surface of the portion.	p. 9, lines 11-12 and 15-17; p. 10, lines 7-10; p. 10, lines 16-21; p. 17, lines 10-15; p. 20, lines 2-4.	Fig. 1, numerals 30, 32 and 38.

Although references to the specification and drawings as filed are given in accordance with 37 C.F.R. 41.37(c)(1)(v), the cited passages and drawings are merely examples of where support may be found in the specification for the terms used in this section of the Brief. There is no intention of suggesting in any way that the claim terms are limited to the examples in the specification. As demonstrated by these references, the claims are fully supported by the specification as required by law. However, it is improper under the law to read limitations from

the specification into the claims. Pointing out support in the specification for claim terms is intended to comply with the patent rules and is not intended in any way to limit the scope of the claims to the examples from which they find support.

## **VI. Grounds of Rejection to be Reviewed on Appeal**

1. Whether there is error in the rejection of Claim 1 under §102(e) as anticipated by U.S. Pat. Appl. Publ. 2005/0245897 to Lee Bolduc et al. (“Bolduc”). Claims 2-10 and 13-15 depend from Claim 1 and are included in this ground. Claim 11 is rejected under 35 U.S.C. §103(a) as unpatentable in view of Bolduc and U.S. Pat. Appl. Publ. 2005/0199110 to Michael Basta (“Basta”). Claim 11 is not separately appealed and stands or falls with Claim 1.

2. Whether there is error in the rejection of Claim 16 under §102(e) as anticipated by U.S. Pat. Appl. Publ. 2005/0245897 to Lee Bolduc et al. (“Bolduc”). Claims 17-22 and 45 are included in this ground.

3. Whether there is error in the rejection of Claim 23 under §102(e) as anticipated by U.S. Pat. Appl. Publ. 2005/0245897 to Lee Bolduc et al. (“Bolduc”). Claims 24-30 depend from Claim 23 and are included in this ground.

## **VII. Argument**

1. Whether there is error in the rejection of Claim 1 under §102(e) as anticipated by U.S. Pat. Appl. Publ. 2005/0245897 to Bolduc. This grouping includes Claims 2-11 and 13-15.

### Legal Standard

35 U.S.C. §102(e) states that a person shall be entitled to a patent unless

(e) the invention was described in - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

In order to make out a prima facie case of anticipation, the reference must anticipate all the elements of the claimed invention. M.P.E.P. 2121. A claim is anticipated only if each and every element as set forth in the claim is found in a single prior art reference. M.P.E.P. 2131, citing *Verdegall Bros. v. Union Oil Co. of Calif.*, 814 F.2d 628, 631 (Fed. Cir. 1987). Bolduc does not include, within the corners of a single prior art document, every element of the claimed invention arranged or combined in the same way as the claimed invention and thus does not anticipate the claims of the present application, as discussed below. *Net Moneyin, Inc. v. Verisign, Inc.*, No. 2007-1565, slip op. at 14, 19 (Fed. Cir. October 20, 2008). Appellants are thus entitled to a patent as provided for under §102.

The present application does not use the terms “proximal” and “distal.” Bolduc uses the term “proximal” to describe a portion of a catheter that has a larger diameter and uses the term “distal” to describe a portion of a catheter with a smaller diameter. See paragraph [0022] and Figs. 2 and 7, in which portions having a larger diameter are external to the patient’s body or nearer the patient point of entry. Portions having a smaller diameter are farther into the patient’s body and farther from the point of entry into the patient. Bolduc thus uses the terms “proximal” and “distal” in their usual medical sense of nearer or farther from the point of entry to the patient. See Stedman’s Medical Dictionary, 27th ed. at 529 and 1468. In adapting these terms to the present application, an object that is “distal” is analogous to an object that is “intraperitoneal,” inside the patient’s peritoneum; an object that is “proximal” is analogous to an object that is “extraperitoneal,” or outside the patient’s peritoneum, e.g., external to the patient’s body.

Independent Claim 1 recites a generally tubular catheter having first and second ends and an insert filling a majority of an interior space defined by the catheter. In Fig. 1, the left-hand portions of the catheter 10 and the insert 30 are consistent with this use, i.e., the left hand side depicts the extraperitoneal portions, while the right hand side depicts the intraperitoneal portions. Per Fig. 1 of the present application, one embodiment of catheter 10 comprises a first plurality of side apertures 28 on the intraperitoneal (inner) end, depicted on the right side of catheter 10. Insert 30 includes a second plurality of side apertures 40 on the extraperitoneal (outer) end, depicted on the left-hand portion of insert 30. This placement of the apertures is designed so that

as seen in Fig. 1 and as explained in the application at p. 10, line 30 to p. 11, line 3, at least a portion of apertures 28 of catheter 10 reside along the bottom of the patient's peritoneal cavity.

The rejection, on p. 2, lines 12-17, states that Bolduc anticipates Claim 1 because Bolduc teaches, in Figs. 1, 7, and 11, a catheter 60 having a cuff 61, an insert 22 having a plurality of apertures 80, 90, on the intraperitoneal and extraperitoneal ends, and a plug 40. Appellants respectfully submit there is error in the rejection of Claim 1, as set forth below, because Bolduc is missing many of the elements of the catheter and insert as claimed.

Bolduc does not disclose or even suggest the claimed catheter

Bolduc Fig. 2 is useful in discussing the rejection and in demonstrating why Bolduc does not anticipate Claim 1. As best seen in the top portion of Fig. 2, the sheath 60 cited in the rejection has side apertures 64 on the right side, as does outer tube 30 with apertures 80 on its right side and inner catheter 22, with side apertures 90 on its right side, toward the bottom of Fig. 2. Thus, all of Bolduc's side apertures are near the right or distal end, i.e., the end further into the patient and farther away from the point of entry to the patient's body, as also seen in Fig. 7 of Bolduc. None of the apertures are on the proximal or left portion, i.e., the portion that would act as the external or extraperitoneal end. Note that apertures 80 of outer tube 30 are specifically described in paragraph [0078] as residing in the distal portion of the tube and are useful for delivering a therapeutic agent from port 38 to the patient. Bolduc does not teach or suggest Claim 1 of the present application because Bolduc's catheters all have apertures placed on the distal or intraperitoneal portion, with none near the proximal or extraperitoneal portion. Bolduc teaches the opposite of the Claim 1 and thus cannot anticipate Claim 1.

Bolduc's outer sheath 60 also cannot anticipate the catheter of Claim 1. Outer sheath 60 is described in Bolduc as an outer sheath used to percutaneously access vasculature of a patient at the introductory site, e.g., a femoral artery. Paragraph [0076], lines 9-12; see also paragraph [0082], stating that the sheath is only used to achieve vascular access, after which the guiding catheter is used. As further seen in Fig. 7, outer sheath 60 does not extend to the distal portion of the access, which is achieved by guide catheter 50 and catheter 22. Thus, the apertures of sheath 60 do not extend sufficiently so that "the catheter comprises a first plurality of side apertures on the intraperitoneal end of the insert," because the outer sheath 60 is used only for a very limited



vasculature access, not to guide catheter 22 to the distal portion of the vasculature where the obstruction exists. See also Bolduc Fig. 8, in which catheter 22 and distal end or tip 26 has extended to a blood vessel occlusion with outer portion side apertures 80, and inner portion side apertures 90. See also text at paragraph [0082] for Fig. 8. Apertures 80 and 90 cannot be interpreted as proximal or extraperitoneal apertures.

Figs. 10-11 of Bolduc depict the distal or internal end of perfusion conduits and do not depict the proximal or external portions. See paragraphs [0044]-[0045] and [0085]-[0086]. In Figs. 10-11 of Bolduc, inner tubes 202, 302 have side apertures 206, unnumbered, or 314, only on the right side, which are distal or distal or intraperitoneal, while outer tubes 204, 304 also have side apertures 208 or none, on the only portion shown, the right side, which are still distal or intraperitoneal. See also Bolduc Figs. 8 and 9, which also depict only distal or intraperitoneal or apertures, 80, 90 or unnumbered.

Bolduc does not teach or even suggest the insert as claimed

The insert as claimed is “sized relative to the interior surface of the catheter to achieve a snug fit between the interior surface of the catheter and the exterior surface of the insert.” A snug fit is described on p. 9, lines 18-23 as filed. A snug fit, in one embodiment, is a clearance of about one tenth of a millimeter on each side between the inner diameter of the catheter and the outer diameter of the elongated tube or insert.

Bolduc Fig. 2 depicts a guide catheter 50 that fits in the space between Bolduc’s sheath 60 and the catheter 22. Because the guide catheter occupies this space, there can be no “snug fit” between the interior surface or inside of the catheter and the exterior of the insert. There can be no snug fit because the inner surface of Bolduc’s guide sheath can only fit against the guide catheter 50; the outer surface of Bolduc’s catheter 22 can only fit against the guide catheter 50.

Claim 1 specifies that the catheter includes “a passageway defined by an interior surface extending from the first end to the intraperitoneal portion,” or second end, and also includes “an insert extending along the passageway and comprising an elongated portion having an exterior surface.” The exterior surface of the insert and the interior surface of the catheter thus define a passageway extending from the first end to the intraperitoneal portion and an insert extending along the passageway, that is, the interior and exterior surfaces extend for some distance or

length. The final rejection cites Bolduc Fig. 11 as disclosing a snug fit, with inner tube 302 exiting perfusion conduit 300 via sliding seal 310. But the sliding seal cannot anticipate the claimed snug fit because it does not extend along a passageway and does not extend from the first end to the peritoneal portion. There is thus error in the rejection of Claim 1 since Bolduc does not teach the claimed insert.

Accordingly, Bolduc does not anticipate the catheter or the insert as recited in Claim 1. The Office Action thus fails to make out a prima facie rejection of Claim 1 and there is error in the rejection of Claim 1 and of dependent Claims 2-11 and 13-15. Because the rejection does not meet the legal standard set forth above in 35 U.S.C. §102(e), Appellants are entitled to a patent for Claims 1-11 and 13-15. Appellants request the Board to reverse the rejections.

2. Whether there is error in the rejection of independent Claim 16 under §102(e) as anticipated by U.S. Pat. Appl. Publ. 2005/0245897 to Lee Bolduc et al. ("Bolduc"). This grouping includes dependent Claims 17-22 and 45.

The Office Action rejects Claim 16 under the same reasoning used above for Claim 1, citing again Figs. 1, 7 and 11. Claim 16 recites three distinct elements, including a generally tubular catheter; an insert placed inside the catheter, the insert defining a cavity; and a guide placed in the cavity and extending from the peritoneal end of the insert. As shown in Fig. 1, the guide 50 includes thin rod portion 52 and a ring portion or handle 54. See application, p. 10, lines 24-26.

Per the discussion above for Claim 1, Bolduc does not anticipate the tubular catheter and the insert of Claim 16. Bolduc also does not disclose the guide recited in Claim 16. The rejection states merely that Bolduc teaches a guidewire, citing the abstract. Office Action, p. 2, line 16. Bolduc's abstract states that "the device of the present invention may also be advanced through small vessels without the aid of a guidewire although a guidewire may be used when necessary." Abstract, lines 3-6. This passage does not teach or suggest the claimed guide, which includes a rod portion and a ring portion or handle.

It is possible that the Office Action intends to imply that Bolduc inherently discloses a guide having a ring or handle as claimed, without specifically stating so. To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present

in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). There are many examples of wire guides or guides that do not have a ring or handle as claimed. See, e.g., U.S. Pat. No. 6,805,676, depicting guide wires with a proximal handle or end that does not include a ring.

Accordingly, the Office Action fails to make out a prima facie rejection because Bolduc does not include, within the corners of a single prior art document, every element of the claimed invention arranged or combined in the same way as the claimed invention and thus does not anticipate the claims of the present application. *Net Moneyin, Inc. v. Verisign, Inc.*, No. 2007-1565, slip op. at 14, 19 (Fed. Cir. October 20, 2008).

There is thus error in rejecting Claim 16. Appellants request this Board to reverse the rejection of Claim 16 because Bolduc does not teach a catheter set as claimed. Claims 17-22, depending from Claim 16 and included in this grouping, are allowable at least because they depend from Claim 16.

3. Whether there is error in the rejection of Claim 23 under §102(3) as anticipated by U.S. Pat. Appl. Publ. 2005/0245897 to Lee Bolduc et al. (“Bolduc”). This group includes dependent Claims 24-30.

Claim 23 recites an obstructor for occupying space within a tubular catheter when inserted into a patient. The obstructor comprises a tube extending along the interior space of the catheter, the tube including an extraperitoneal end and an intraperitoneal end, a portion near the extraperitoneal end having an increased diameter and a plurality of side apertures, with additional claim elements.

The Office Action rejects Claim 23 in the same rejection with Claims 1 and 16, citing a plug 40, depicted in Bolduc Figs. 2 and 7. Bolduc describes a proximal port 40, typically a hemostatis valve, as communicating with the lumen of the inner tubular member 32 and suitable for intravascular positioning of the catheter 22 over a guide wire. See paragraph [0075]. Port 40 is not further described, but the proximal end of catheter 22 also includes additional ports 36, 38 fluidly coupled to the catheter. See *id.* A port is defined as an opening for intake or exhaust of a fluid. Merriam-Webster’s Collegiate Dictionary, 10th ed. at 907. A valve is defined as any one of numerous mechanical devices by which the flow of liquid, gas or loose material in bulk may

be started, stopped or regulated by a movable part that opens, shuts, or partially obstructs one or more ports or passageways. *Id.* at 1305.

Thus, a valve or port as described in Bolduc may be considered as a device at an end of a lumen for regulating flow to and from the lumen, as shown in Bolduc. There is no teaching or suggestion, however, that such a device "extends along the interior space" of the lumen or of a catheter, as claimed. Bolduc does not teach an obstructor as recited in Claim 23. Accordingly, the Office Action fails to make out a *prima facie* rejection because Bolduc does not include, within the corners of a single prior art document, every element of the claimed invention arranged or combined in the same way as the claimed invention and thus does not anticipate the claims of the present application.

Bolduc does not teach or suggest all the limitations of Claim 23 and thus there is error in the rejection of Claim 23 and dependent Claims 24-30.

Appellants respectfully submit that there is error in the rejection of at least Claims 1, 16 and 23 as anticipated under 35 U.S.C. §102(e). In addition, Appellants respectfully submit that there is error in rejecting dependent Claims 2-11, 13-15, 17-22, 24-30 and 45 because they depend from allowable Claims 1, 16 and 23. The rejection of Claims 1-11, 12-30 and 45 is thus error. Accordingly, Appellants respectfully submit that the rejections are erroneous in law and fact and should therefore be reversed by this Board.

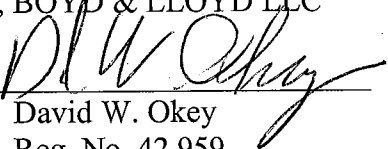
The Director is authorized to charge any other fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818.

February 19, 2009

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY

  
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### **VIII. Claims Appendix**

#### **PENDING CLAIMS OF U.S. PAT. APPL. SERIAL NO. 10/535,034**

Claim 1 (previously presented): A catheter set for peritoneal dialysis comprising:

a generally tubular catheter having first and second ends, an extraperitoneal portion near the first end and an intraperitoneal portion near the second end and a passageway defined by an interior surface extending from the first end to the intraperitoneal portion; and

an insert extending along the passageway and comprising an elongated portion having an exterior surface which is sized relative to the interior surface of the catheter to achieve a snug fit between the interior surface of the catheter and the exterior surface of the insert, the insert defining a cavity and having an extraperitoneal end and an intraperitoneal end wherein the catheter further comprises a first plurality of side apertures formed on the intraperitoneal portion of the catheter and wherein the insert further comprises a second plurality of side apertures formed near the extraperitoneal end, the cavity being in fluid communication with the second plurality of side apertures.

Claim 2 (original): The set of Claim 1, which includes a plug placed in the extraperitoneal end of the insert after the catheter and insert have been implanted in a patient.

Claim 3 (original): The set of Claim 1, wherein the intraperitoneal end of the insert is open or closed.

Claim 4 (previously presented): The set of Claim 1, wherein the intraperitoneal section further comprises a coiled end or at least one disc extending perpendicularly from the peritoneal section.

Claim 5 (original): The set of Claim 1, which includes a guide placed in the cavity of the insert before the catheter and insert have been implanted in the patient.

Claim 6 (original): The set of Claim 1, wherein at least one of the insert and the plug includes a radio opaque member.

Claim 7 (Previously presented): The set of Claim 1, wherein a subcutaneous portion of the extraperitoneal section is straight or is curved.

Claim 8 (original): The set of Claim 1, wherein the catheter is a tube and the insert fills most of an open space defined by the tube.

Claim 9 (original): The set of Claim 1, which includes a syringe for injecting a liquid into the cavity.

Claim 10 (previously presented): The set of Claim 1, wherein the first plurality of apertures are grooves.

Claim 11 (Previously presented): The set of Claim 1, wherein the catheter further comprises at least one cuff for promoting tissue ingrowth.

Claim 12 (cancelled)

Claim 13 (original): The set of Claim 11, wherein at least one aperture is an elongated flute.

Claim 14 (original): The set of Claim 1, wherein the insert is at least as long as the catheter.

Claim 15 (original): The set of Claim 1, which includes at least one piece of surgical string securing the catheter and the insert.

Claim 16 (previously presented): A catheter set for peritoneal dialysis comprising:  
a generally tubular catheter having first and second open ends and comprising an extraperitoneal portion near the first end and an intraperitoneal portion near the second end and a passageway defined by an interior surface extending from the first end to the second end, and a first plurality of side apertures formed near the second end;

an insert placed inside the catheter, the insert extending along the passageway and comprising an elongated portion having an exterior surface which is sized relative to the interior surface of the catheter to achieve a snug fit between the interior surface of the catheter and the exterior surface of the insert, the insert defining a cavity and having an extraperitoneal end and an intraperitoneal end and a second plurality of side apertures formed near the extraperitoneal end; and

a guide placed in the cavity and extending from the extraperitoneal end of the insert.

Claim 17 (original): The catheter set of Claim 16, wherein the guide is metal.

Claim 18 (original): The catheter set of Claim 16, which includes a trocar secured to the extraperitoneal end of the insert when the guide has been removed.

Claim 19 (original): The catheter set of Claim 16, wherein the guide defines a portion configured and arranged to be grasped and moved by a person.

Claim 20 (original): The catheter set of Claim 16, wherein the catheter includes at least one cuff.

Claim 21 (original): The catheter set of Claim 20, wherein the cuff includes at least one of a bead and a flange.

Claim 22 (original): The catheter set of Claim 16, wherein a portion of the catheter and insert is coiled.

Claim 23 (Previously presented): An obstructor for occupying space within a tubular catheter when inserted into a patient, the catheter defining first and second ends and a passageway defined by an interior surface extending between the first and second ends, the obstructor comprising:

a tube extending along the interior space of the catheter, the tube including an extraperitoneal end and an intraperitoneal end, a portion near the extraperitoneal end having an

increased diameter and a plurality of side apertures, the portion contacting the first end of the catheter when the tube is inserted into the catheter, the intraperitoneal end of the tube extending at least substantially to the second end of the catheter, an outer diameter of the portion having an exterior surface which is sized relative to the interior surface of the catheter to achieve a snug fit between the interior surface of the catheter and the exterior surface of the portion.

Claim 24 (original): The obstructor of Claim 23, wherein the larger diameter portion is sized to press-fit inside the catheter.

Claim 25 (original): The obstructor of Claim 23, wherein the tube houses a radio opaque member.

Claim 26 (original): The obstructor of Claim 23, wherein the tube is a first tube and the larger diameter portion is a second tube adhered to the first tube.

Claim 27 (Previously presented): The obstructor of Claim 23, wherein the tube is made from at least one material selected from the group consisting of: silicone, a fluoropolymer, polyurethane, polypropylene, metal mesh, metal spiral, and any combination thereof.

Claim 28 (Previously presented): The obstructor of Claim 23, wherein the tubular catheter further comprises an intraperitoneal end having a coiled end or at least one disc extending perpendicularly from the intraperitoneal section.

Claim 29 (original): The obstructor of Claim 23, which includes a plug inserted into the extraperitoneal end.

Claim 30 (Previously presented): The obstructor of Claim 23, wherein the tubular catheter further comprises a plurality of side apertures on the second end.

Claim 31 (withdrawn): A method for inserting a catheter comprising the steps of: making an incision into a patient;



inserting the catheter, the catheter having an insert filling most of the internal space defined by the catheter; and

removing the insert after the catheter has been implanted.

Claim 32 (withdrawn): The method of Claim 31, wherein a guide is placed initially into the insert; and which includes the steps of using the guide to maneuver the catheter inside the patient and then removing the guide.

Claim 33 (withdrawn): The method of Claim 31, wherein the insert includes a tubular length and at least one hole defined by the tubular length, and which includes the step of injecting fluid into the tubular length, through the hole between the insert and the catheter.

Claim 34 (withdrawn): The method of Claim 33, which includes the step of placing a plug in the insert after injecting the fluid into the insert.

Claim 35 (withdrawn): The method of Claim 33, which includes the step of removing the insert after injecting the fluid.

Claim 36 (withdrawn): The method of Claim 31, wherein at least one cuff is positioned on the catheter, and which includes the step of securing the cuff to the patient.

Claim 37 (withdrawn): The method of Claim 31, which includes making a plurality of incisions into the patient and the step of using the multiple incisions to guide the catheter in a plurality of directions.

Claim 38 (withdrawn): The method of Claim 37, which includes the step of using an instrument to bend the catheter inside the patient.

Claim 39 (withdrawn): The method of Claim 31, which includes the step before removing the insert of closing the insertion with the catheter and insert implanted inside the patient.

Claim 40 (withdrawn): The method of Claim 31, wherein removing the insert occurs after a period of time in which the insert and catheter have resided inside the patient.

Claim 41 (withdrawn): The method of Claim 31, which includes the step of flushing the catheter after the insert has been removed.

Claim 42 (withdrawn): The method of Claim 31, which includes the step of securing one end of the catheter to reside outside the body of the patient after the insert has been removed.

Claim 43 (withdrawn): The method of Claim 31, wherein the catheter is preformed to have a bead, wherein inserting the catheter includes inserting the preformed catheter.

Claim 44 (withdrawn): A method of implanting a catheter comprising the steps of:  
implanting the catheter inside a patient, the catheter having an obstruction tending to disallow material from entering the catheter;  
leaving the entire catheter inside the patient for a period of time; and  
removing the obstruction and securing a portion of the catheter to extend outside the patient.

Claim 45 (Previously presented) The catheter set of Claim 16, wherein the first plurality of apertures are grooves.

## **IX. Evidence Appendix**

**None**

## **X. Related Proceedings Appendix**

**None**